



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): HILDEBRAND et al. Group Art Unit: 1616  
Patent No.: 10/808,113 Examiner: David Paul Stitzel, Esq.  
Filed: March 24, 2004 Docket No.: 134.02510101 (P-20907.00)  
Confirmation No.: 4515  
Title: PROCESS FOR PRODUCING INJECTABLE GABAPENTIN COMPOSITIONS

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

We are transmitting the following documents along with this Transmittal Sheet (which is submitted in triplicate):

- ☒ An itemized return postcard.  
☐ A Petition for Extension of Time for \_\_ month(s) and a check in the amount of \$\_\_ for the required fee.  
☒ An Information Disclosure Statement (2 pgs); copy of International Search Report (4 pgs); 1449 form (1 pg); and copies of 7 documents cited on the 1449 form.  
☐ A request for continued examination (RCE) and a check in the amount of \$, for the required filing fee.  
☐ An Appeal Brief and a check in the amount of \$, for the required Appeal Brief filing fee.  
☐ A check in the amount of \$\_\_, for \_\_.  
☐ A certified copy of a \_\_ application, Serial No. \_\_, filed \_\_\_\_, the right of priority of which is claimed under 35 U.S.C. §119.  
☐ Other:  
☐ Amendment \_\_ No Additional fee is required. \_\_ The fee has been calculated as shown:

Fee Calculation for Claims Pending After Amendment					
	Pending Claims after Amendment (1)	Claims Paid for Earlier (2)	Number of Additional Claims (1-2)	Cost per Additional Claim	Additional Fees Required
Total Claims				x \$50 =	
Independent Claims				x \$200 =	
One or More New Multiple Dependent Claims Presented? If Yes, Add \$360 Here →					
Total Additional Claim Fees Required					

Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers and please charge any additional fees or credit overpayment to Deposit Account No. 13-4895. Triplicate copies of this sheet are enclosed.

**CERTIFICATE UNDER 37 C.F.R. §1.8:** The undersigned hereby certifies that this Transmittal Letter and the paper(s), as described hereinabove, are being deposited in the United States Postal Service, as first class mail, in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 24th day of January, 2006.

MUETING, RAASCH & GEBHARDT, P.A.  
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PATENT  
Docket No. 134.02510101 (P-20907.00)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Serial No.: 10/808,113 )  
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COMPOSITIONS )

Group Art Unit: 1616  
Examiner: David Paul Stitzel, Esq.

INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

01/27/2006 HDEMESS1 00000020 134895 10808113

01 FC:1806 Sir: 180.00 DA

In compliance with the duty imposed by 37 C.F.R. § 1.56, and in accordance with C.F.R. §§ 1.97 *et. seq.*, the materials enclosed herewith are brought to the attention of the Examiner as possibly being of interest in connection with the above-identified patent application. Also enclosed is a copy of an International Search Report from related foreign application PCT/US2004/034690. Per M.P.E.P. §609, the information cited in the present Information Disclosure Statement shall not be construed to be an admission that the information is, or is considered to be, material to patentability. Consideration of each of the documents listed on the attached 1449 forms is respectfully requested. Pursuant to the provisions of M.P.E.P. §609, Applicant further requests that a copy of the 1449 forms, marked as being considered and initialed by the Examiner, be returned with the next Official Communication.

Since this Information Disclosure Statement is submitted after the receipt of an Office Action in the above-identified patent application, please charge the fee of \$180 under 37 C.F.R. §§1.97(c) and 1.17(p), or charge any additional fees, or credit any overpayment, to Deposit Account No. 13-4895.

**Information Disclosure Statement**

Applicant(s): HILDEBRAND et al.

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Page 2 of 2

The Examiner is invited to contact Applicants' Representatives at the below-listed telephone number if they can be of any assistance during prosecution of the present application.

**CERTIFICATE UNDER 37 C.F.R. 1.8:**

The undersigned hereby certifies that this paper is being deposited in the United States Postal Service, as first class mail, in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 24<sup>th</sup> day of January, 2006.

KW Raasch  
Kevin W. Raasch

January 24, 2006  
Date

KWR/skd

Respectfully submitted

By

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<b>INFORMATION DISCLOSURE STATEMENT</b>	<b>Atty. Docket No.:</b> 134.02510101 (P-20907.00)	<b>Serial No.:</b> 10/808,113
	<b>Applicant(s):</b> HILDEBRAND et al.	<b>Confirmation No.:</b> 4515
	<b>Application Filing Date:</b> March 24, 2004	<b>Group:</b> 1616
	<b>Information Disclosure Statement mailed:</b> January 24, 2006	

**U.S. PATENT DOCUMENTS**

Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
		4,024,175	05/17/77	Satzinger et al.			
		6,054,482	04/25/00	Augart et al.			

**FOREIGN PATENT DOCUMENTS**

Examiner Initial	Copy Enclosed	Document Number	Date	Country	Class	Subclass	Translation	
							Yes	No
	✓	WO 98/28255	07/02/98	PCT				
	✓	WO 00/57927 A1	10/05/00	PCT (English language abstract only)				X
	✓	WO 02/100347 A2 & A3	12/19/02	PCT				
	✓	WO 03/061656 A1	07/31/03	PCT				
	✓	WO 03/070237 A1	08/28/03	PCT				

**OTHER DOCUMENTS (Including Authors, Title, Date, Pertinent Papers, etc.)**

Examiner Initial	Copy Enclosed	Document Description
	✓	Lagreze et al., "The neuroprotective properties of gabapentin-lactam," <i>Graefe's Arch. Clin. Exp. Ophthalmol.</i> , 2001; 239(11):845-849.
	✓	Li et al., Database Medline/NLM, Bethesda, MD, "Moist-heat sterilization and the chemical stability of heat-labile parenteral solutions," Database Accession No. NLM15605602 abstract, 1 pg.

<b>EXAMINER</b>	<b>Date Considered</b>
<p><b>*Examiner:</b> Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>	